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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,961	01/18/2002	Joseph R. Berger	44657-AAA-PCT-US/JPW	3958

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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/052,961	BERGER, JOSEPH R.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/20/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' remarks and the declaration under 37 C.F.R. 1.132 submitted May 20, 2008 is acknowledged.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 89-105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims are drawn to a unit dosage form, tablet, comprising 10 mg of oxandrolone, corn starch, hydrous lactose, hydroxypropyl methylcellulose, and magnesium stearate. The application have single example of tablet which is composed of 2.5 mg of oxandrolone, and specific amount of corn starch, hydrous lactose, hydroxypropyl methylcellulose, and magnesium stearate (page 7). The application merely mentions 10-milligram dosage, but does not disclose any further information as to the carrier and particular forms (page 4, the first paragraph). Therefore, the application as originally filed, lack support of a unit dosage form, or tablet comprising 10 mg of oxandrolone, and one of more of corn starch, hydrous lactose, hydroxypropyl methylcellulose, and stearate, nor to the particular amounts of the carriers

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 88-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Metcalf et al. (of record), in view of ANAVAR® (of record, provided by applicant in IDS filed October 13, 2005), and Babu et al. (US 5,073,380) and in further view of applicants' admission at page 7.

Metcalf teach a method of using oxandrolone for nitrogen retention wherein the daily of amounts of oxandrolone are from 5 mg, 10 mg, 20 mg, and up to 150 mg. Oxandrolone were taken as single dosage daily. See, particularly, Method at page 60. Metcalf also teach that the optima dosage is about 25 mg or 30 mg a day.

Metcalf et al. do not teaches expressly a dosage forms comprising 10 mg of oxandrolone and the particular pharmaceutical excipients herein.

However, Anavar® disclosed an oxandrolone tablet, wherein the inactive ingredients includes corn starch, lactose, magnesium stearate and methylcellulose. Anavar® further reveals that daily dosage of oxandrolone may be up to 20 mg/day. See the entire document. Babu et al. disclosed that hydroxypropyl methylcellulose is a typical excipient for tablet formulation. See, column 2, lines 6-8. Further, applicants admitted that tablet formulation comprising oxandrolone, corn starch, hydrous lactose, hydroxypropyl methylcellulose and magnesium stearate is known in the art. See, page 7.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art, at the time the claimed invention was made, to make a dosage composition comprising 10 mg of oxandrolone, and the particular excipients herein as the excipients herein are well-known pharmaceutical excipients and are particularly known to be useful in solid dosage forms with oxandrolone.

The 10 mg dosage would have been obvious in view the fact that it has been used in the amount of 10 mg, 20 mg, and up to 150 mg daily. One of ordinary skill in the art would have been motivated to make a tablet with 10 mg of oxandrolone for those uses more than 10 mg a day.

As to the intended use recited in the claims (for daily dosage, or not), note it is well settled that the "intended use" of a product or composition will not further limit claims drawn to a product or composition. See, e.g., In re Hack 114 USPQ 161.

Response to the Arguments

4. The declaration under 37 C.F.R. 1.132 and the remarks submitted May 20, 2008 have been fully considered, but are not persuasive.

5. Applicants' arguments regarding the new matter rejections are not persuasive as it is well-settled that a broad and general disclosure of a genus would not support a species encompassed by the genus. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967). Also see MPEP 2163.05.

6. The declaration under 37 CFR 1.132 filed May 20, 2008 is insufficient to overcome the rejection of claims 88-105 based upon Metcalf et al. (of record), ANAVAR®, Babu et al. (US

5,073,380) and applicants' admission at page 7 as set forth in the last Office action because: a prima facie case of obviousness for claimed invention: 10 mg dosage form of oxandrolone, has been established, as administration of 10 mg or more of oxandrolone daily would have been obvious. The "pill-burden" issues are not sufficient to rebut the prima facie case of obviousness, as a merely change of size, shape of a subject matter would not make the subject matter patentably distinguish. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

7. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Particularly, the prior art teach a broad range of daily dosage of oxandrolone from 5 mg to 150 mg, with preferred daily dosage of 25-30 mg. First the 10 mg daily dose would have been obvious as it is within the disclosed range of prior art. The optimization of a result effective parameter, e.g., effective amount of a therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. One of ordinary skill in the art would have recognized that a 10 mg of oxandrolone daily would be optimal for patient with lower body weight, such as young children. Furthermore, the examiner maintains that a 10 mg oxandrolone tablet would have been obvious for a preferred 25-30 mg daily dosage recommendation as it provide more options to patients, as adult patients may

take one tablet a time and three time a day, or take three tablets a time for the whole day, and young children may just take one tablet.

Regarding "pill-burden" issues, as discussed above, the pill-burden issues, i.e., making a single larger dosage, rather than a plural of smaller dosage, are not sufficient to overcome the prima facie case of obviousness.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617